

Report to the U.S. Congress

on

**the Import Equivalence and
Reinspection Processes**

of

**the U.S. Department of Agriculture's
Food Safety and Inspection Service**



March 2004



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Table of Contents

Introduction	Page 2
Background.....	Page 3
Foreign Inspection System Audits.....	Page 3
Port-of-Entry Reinspection.....	Page 6
Summary.....	Page 7

Attachments

List of Equivalent Countries.....	1
Example of Equivalence Audit Cover Letter and Questionnaires.....	2
Example of Audit Checklists for Initial Equivalence.....	3
Example of Proposed Rule.....	4
Example of Decision Memorandum.....	5
Reinspection Data from FY 1999-2003.....	6

Food Safety and Inspection Service Import Equivalence and Reinspection Processes

Introduction

The Conference Report (H. Rpt. 108-401) accompanying the Consolidated Appropriations Act of 2004 (P.L. 108-199), directed the Food Safety and Inspection Service “*to report to the Committees by March 1, 2004, on the equivalence and reinspection processes. The report should address: how the agency determines that a country's meat inspection system is equivalent; whether this determination is subject to regular review and if so, how; what process FSIS uses for determining that a country is no longer equivalent; what public review of FSIS's equivalency determinations exists; why the amount of meat reinspected at the border has declined sharply; and how the agency's new automated import information system has impacted inspection operations at the border.*”

This report reviews the efforts of the U. S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) to ensure the safety of imported meat, poultry, and egg products.

Background

FSIS regulation of imports is multi-faceted and provides several tools for ensuring the safety of imported meat, poultry, and egg products. The agency's main focus is on the foreign country's inspection system. The systems approach has been used since the 1980s when FSIS concluded that the most effective way to ensure that imported meat, poultry, and egg products met U.S. food safety requirements was to place responsibility with the foreign government to carry out an equivalent inspection system. FSIS needed to design a program that would place responsibility with the foreign government and, at the same time, would allow FSIS to monitor and verify the effectiveness of the foreign inspection system. FSIS does this through two main activities: audits of the foreign inspection system and port-of-entry reinspection.

Meat, poultry, and egg products exported to the U.S. must meet all safety standards applied to foods produced in the U.S. While foreign food regulatory systems do not need to be identical to the U.S. system, they must employ equivalent measures that provide the same level of protection against food safety hazards. FSIS evaluates foreign food regulatory systems for equivalence through document reviews, on-site audits, and port-of-entry reinspection of product. Currently, there are 32 countries that we determined have inspection systems equivalent to the U.S., and therefore, are eligible to export meat, poultry, and/or egg products to the United States (see Attachment 1).

Foreign Inspection System Audits

Initial Equivalence Audits

Any country can apply for eligibility to export meat, poultry, or egg products to the United States. Normally, the application process begins with a letter to FSIS from a foreign government asking for clearance to export its products for sale in U.S. commerce. FSIS responds to these letters with a standard package consisting of questionnaires (see Attachment 2) designed to collect detailed information about the foreign food regulatory system; examples of completed questionnaires that demonstrate how FSIS would answer them; and copies of pertinent U.S. laws, regulations, and other documents. The initial package provides an applicant country with information about the U.S. meat, poultry, and egg products food regulatory system and conveys expectations about sanitary measures that FSIS anticipates in an equivalent foreign system. In summary, the initial eligibility package explains by example the level of sanitary protection that FSIS deems appropriate.

Foreign countries often take months to compile the necessary information and complete the questionnaires. Upon request, FSIS provides advice and guidance to foreign governments concerning any portion of the application process. When the completed application is received, FSIS conducts an initial document analysis. In many cases, further information or clarification is needed. FSIS advises the foreign government of data or other information needed to finish the evaluation, and works collaboratively with its food regulatory officials to facilitate this process. Upon completion of the document analysis step, FSIS makes a decision as to whether the foreign food regulatory system documentation (1) meets all U.S. import requirements in an equivalent manner, and (2) cumulatively provides the same level of public health protection attained domestically. If this step is satisfactorily completed, FSIS would then carry out an on-site audit of the entire foreign meat, poultry, and/or egg products food regulatory system.

Initial equivalence audits are conducted by a multidisciplinary team of experts. Composition of the audit team may include a veterinarian, food technologist, microbiologist, chemist, residue technician, compliance officer, document analysis case officer, and others as needed. In some instances, auditors may possess multiple skills and will perform more than one function. The audit planning process begins with each auditor becoming completely familiar with all documentation submitted by the foreign government. The audit scope includes system records such as country laws, regulations, notices, and other program implementation documents; records of establishment operations, inspection results, and enforcement activities; chemical residue controls from farm to slaughter; microbiological and chemical testing programs; laboratory support; sampling programs; testing methodologies; and special U.S. import requirements such as pathogen reduction and Hazard Analysis and Critical Control Point (HACCP) programs (see Attachment 3). Data collection instruments are devised to evaluate each foreign food regulatory system component.

During the on-site audit, FSIS auditors correlate foreign program documentation with observations about program delivery. Thus, the goal of an initial equivalence audit is to verify that the foreign food regulatory system has satisfactorily implemented all the country laws, regulations, and other inspection or certification requirements that FSIS found to be equivalent during the document analysis step. Follow-up audits are conducted when necessary to complete the initial equivalence on-site process.

When both the document analysis and on-site audit steps have been satisfactorily completed, and FSIS determines that a country maintains an inspection system for meat, poultry, or egg products that is equivalent to the United States' inspection system, the agency publishes a proposed rule in the *Federal Register* (see Attachment 4) that announces results of the first two steps and proposes to add the country to its list of eligible exporters. At a minimum, the administrative record, which is available to the public, contains the draft final and final on-site audit reports, any correspondence sent to the country and received from the country, and the decision memorandum recommending that the country be determined to be equivalent (see Attachment 5). The decision memorandum provides the criteria used by FSIS to determine equivalence, including U.S. regulatory requirements evaluated against the foreign country's regulatory requirements. The proposed rule is usually open for public comment for 60 days. Upon receipt of public comments, FSIS makes a decision about system equivalence based upon all available information and publishes a final rule in the *Federal Register* announcing country eligibility.

Annual Equivalence Verification Audits

All foreign food regulatory system equivalence audits are conducted at least annually in four phases: planning, execution, evaluation, and feedback. For example, an annual system equivalence verification audit would consist of the following activities.

1. PLAN. FSIS prepares a consolidated annual plan to audit each country that exports meat, poultry, or egg products to the United States. Individual country audit plans are based, in large part, upon prior experience with the exporting country. For example, all previous FSIS audit reports are reviewed to identify issues for inclusion in the current audit. Port-of-entry reinspection data are also reviewed at this time to determine trends and identify areas of special interest for audit. These documents and data are used by FSIS to develop an audit plan that is customized for each country. The plan includes a list of foreign establishments selected for centralized records review. A subset of these establishments is further selected for on-site audit. FSIS uses a statistical method for

establishment selection. Additional establishments may be added for cause. The audit plan is transmitted to the exporting country for comment before implementation. The audit protocol is sufficiently detailed to inform the exporting country of the audit objectives, scope and criteria, who will be visiting, what they wish to see, where they wish to go, and when they wish to do so. Special emphasis is given to adoption of new sanitary measures or food regulatory system changes that have occurred since the last audit either through initiative of the exporting country or in response to new U.S. import requirements.

2. EXECUTE. An auditor or audit team is dispatched to the exporting country's inspection headquarters and/or to sub-offices as agreed to in the audit protocol. Opening discussions are held with exporting country officials to determine if the national system of inspection, verification, and enforcement is being implemented as documented, and to identify significant trends or changes in operations. The FSIS auditor examines a sample of program records that evidence exporting country regulatory activities, and accompanies country officials on field visits to a representative sample of establishments that are eligible for export to the United States. Exporting country officials conduct a review to verify that each selected establishment continues to achieve the U.S. level of sanitary protection. Particular attention is paid to how eligible establishments address food safety hazards, some of which may be different from those encountered in the United States. FSIS auditors observe establishment activities and correlate review findings made by exporting country officials. Selected microbiological and chemical laboratories are also reviewed, and a farm or feedlot is visited to verify animal drug controls. In a closing meeting, the FSIS auditor provides exporting country officials with an overview of conditions observed and ensures that audit observations are clearly understood.

3. EVALUATE. FSIS conducts a post-audit evaluation of all data collected on-site. When evaluating audit data, FSIS considers how sanitary measures of the foreign food regulatory system compare or contrast to those used in the U.S. and determines whether the foreign system cumulatively provides the same level of protection.

4. FEEDBACK. FSIS next sends the exporting country a draft audit report and provides them an opportunity to comment on its findings. After consideration of the country's comments, a final report is prepared. An action plan is mutually developed to address any issues raised by the audit. These issues are tracked by FSIS until resolution and are automatically included as items of special interest in the next audit.

All equivalence verification audit reports are posted on the FSIS web site (www.fsis.usda.gov) when they are "final," which is immediately after the final version is delivered to the audited country. In some instances, when a more in-depth audit of a country is deemed necessary, FSIS will dispatch an interdisciplinary team of experts to conduct an equivalence verification. Occasionally, a country may be identified for more than one audit per year. These decisions are made on a case-by-case basis.

Suspension of a Country's Eligibility to Import to the U.S.

If FSIS determines, through audits of a foreign inspection program's food regulatory system, that a country is no longer maintaining a system equivalent to the U.S. inspection system, then the Agency may suspend a country's eligibility to export meat, poultry, and egg products to the U.S. FSIS will provide notice to the foreign government of the proposed termination of eligibility for importation

of its products into the United States unless delay in terminating its eligibility could result in the importation of adulterated or misbranded product.

Delistment of Foreign Plants

A foreign plant can be delisted if it were found to have any serious deficiency that shows it is not meeting standards equal to those achieved in U.S. domestic plants. Examples include instances of direct product contamination; poor environmental sanitation that could lead to direct product contamination; lack of a sanitation standard operating procedure or failure to implement an existing procedure; no HACCP plan or an inadequate plan or not following an existing plan; no testing for generic *E. coli*; less than continuous inspection coverage; humane slaughter violations; and any other fundamental requirement of equivalence.

FSIS allows foreign inspection services to recertify a delisted plant upon correction of all deficiencies that resulted in its delistment. During the next annual audit, FSIS visits any plant that was delisted the year before to verify that its deficiencies have been corrected.

Port-of-Entry Reinspection

In FY 2003, 3.8 billion pounds of imported meat, poultry, and processed egg products were presented for entry into the U.S. from 28 of 33 countries eligible to export that year (see Appendix 6). Every shipment of imported meat, poultry, and egg products is visually inspected by an FSIS import inspector who verifies that documents are correct and that both the labeling and the general condition of the shipment are satisfactory. Then, based on a statistical sampling plan, certain lots are subjected to more intense examination, which includes organoleptic evaluation as well as product sampling for food chemistry, microbiological, and residue testing.

AIIS

In 1978, FSIS inaugurated the Automated Import Inspection System (AIIS), which for the first time, provided a link among all the ports and real-time information about the performance of a foreign country's inspection system. That system served the agency well over the years. However, as with any program, it needed to be evaluated and updated.

FSIS was committed to improving the way that meat, poultry, and egg products shipments would be selected for reinspection. It was important that the agency align the port-of-entry sampling program with its overall systems approach to verifying the performance of foreign countries. Thus, FSIS decided to change the focus of the program from an individual plant basis to a systems basis. Since equivalence determinations are based on the foreign country's inspection system, the change would provide a better measure for evaluating the ongoing equivalence of the foreign country's inspection system. In addition, FSIS sought to replace the product codes in the older system with the HACCP process categories used in FSIS' domestic inspection program. Thus, this change would more closely align the FSIS domestic and import inspection programs and allow FSIS to quickly and easily adapt any changes made in its domestic program to its import program as well.

After September 2002, FSIS successfully transitioned to a systems approach from a plant-by-plant approach. The new system uses HACCP categories to classify products based on preparation

procedures in the foreign establishment. The change has strengthened the statistical basis of the sampling program. In looking at the pre-September 2002 system, FSIS analysts concluded that the old system was over-sampling in high volume categories such as fresh beef, while under-sampling in lower volume categories such as ready-to-eat (RTE) products. This occurred because samples were selected either by random selection from among all of the country's imported shipments (as with Canadian imports) or by random selection from an individual plant's shipments. The new system was designed to provide a more valid assessment of the performance of the country's inspection system as a whole. This was accomplished by stratifying the sample population so as to provide a more homogeneous sample frame and to assure that samples were selected from all types of product. For each country, samples are randomly selected from every species/HACCP product category. This contrasts with the previous system, which did not collect a statistically valid number of samples from low-volume categories. Program employees monitor the system by reviewing reports, which demonstrate that appropriate samples are being taken from all product categories. The new sampling program has resulted in fewer shipments being selected for sampling. However, the decrease is consistent with the sampling plan. Countries with a high volume of a single species/HACCP process category, such as fresh beef cuts, have a reduced sampling rate. This has been demonstrated with New Zealand and Australia, and the reduction for those two countries largely accounts for the overall sampling reduction. Nonetheless, FSIS is selecting a statistically valid number of samples from those two countries to provide an accurate picture of the performance of their inspection systems.

Under the new AIIS, a centralized database generates reinspection assignments and stores results. After clearing U.S. Customs and Border Protection and the Animal and Plant Health Inspection Service (APHIS), every imported meat and poultry shipment must be presented to FSIS. When a meat or poultry shipment is presented for reinspection, the AIIS scans its records to verify eligibility. Shipments are denied reinspection and refused entry if the foreign country is not eligible to export to the United States, if the establishment that produced the product has not been certified for export to this country, if the product presented for reinspection is not eligible, if the shipping marks are not unique, or if APHIS has animal health restrictions on the country. Products that fail reinspection are rejected and must be re-exported, converted to non-human food, or destroyed. Product rejections cause the AIIS to automatically generate an increased rate of reinspection for future shipments of like product from the same establishment.

Summary

FSIS has an extensive system in place to determine if foreign countries and individual plants are equivalent to the U.S. system before they are approved to export to the U.S. In addition, the agency's modernized AIIS is allowing FSIS to more efficiently reinspect imported products, without compromising the level of food safety provided by FSIS' previous import reinspection system. FSIS has taken and will continue to take steps to further ensure the safety of imported products from countries that have been deemed eligible to export to the U.S.